



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,882	03/02/2000	DUNCAN MCGREGOR	1015-00	3081

7590 02/11/2003

CHARLES N. QUINN, ESQ.
FOX ROTHSCHILD O'BRIEN & FRANKEL, LLP
2000 MARKET STREET
10TH FLOOR
PHILADELPHIA, PA 19103-3291

EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
----------	--------------

1639

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/486,882

Applicant(s)
McGregor

Examiner
Padmashri Ponnaluri

Art Unit
1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 23, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-23 is/are pending in the application.
- 4a) Of the above, claim(s) 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 18 6) ☐ Other:

Art Unit: 1639

DETAILED ACTION

NOTE: The Examiner, Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1639.

1. The amendment C, filed on 8/23/02, to the claims has been fully considered and entered into the application.
2. Claim 2 has been canceled and claims 1, 3-10 have been amended by the amendment C, filed on 8/23/02.
3. The amendments to the specification filed on 8/23/02 have not been entered.
4. The supplemental amendment filed on 10/8/02 has been considered and is not entered. The substitute specification filed on 10/8/02 has not been entered because it does not conform to 37 CAR 1.125(b) because: "A statement that the substitute specification includes no new matter" was not provided.
5. Claims 1, 3-23 are currently pending in this application.
6. This application contains claims 11-23 are drawn to an invention non elected in Paper No. 16. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CAR 1.144) See MPEP § 821.01.
7. Claims 1, 3-10 are currently being examined in this application.
8. The 35 U. S. C. 112, first and second paragraph rejections of record have been withdrawn in view of the amendments to the claims.

Art Unit: 1639

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 1, 5-6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Schatz et al (US Patent 5,498,530) for the reasons of record.

New Rejections necessitated by the Amendment

11. Claims 5-10 are objected to under 37 CAR 1.75© as being in improper form because a multiple dependent claim can not depend on another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-10 not been further treated on the merit.

12. Claims 4-10 are objected to because of the following informalities: claims 4-10 recite 'any one of the claims 1 and claim 3.... or 1 and 3-5', which is not clear does applicant mean that the claim is dependent on either claim 1 or all the claims. Appropriate correction is required.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1 and 3-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claim 1 recites 'a synthetic construct comprising a recombinant polynucleotide-chimeric protein complex wherein *the chimeric protein has a nucleotide binding portion which comprises a binding domain of a nuclear steroid receptor and a target peptide*

Art Unit: 1639

portion, wherein **said** recombinant polynucleotide comprises a chimeric-protein encoding portion, and a nucleotide sequence motif which is specifically bound by said nucleotide binding portion, and wherein *at least the chimeric- encoding* portion of the recombinant polynucleotide not bound by the chimeric protein nucleotide binding portion is protected by a binding moiety which is protein able to bind to polynucleotides irrespective of the nucleotide sequences.'

The claim is generally narrative and indefinite. It appears to be a literal translation into English from a foreign document. The scope of the invention sought to be patented can not be determined from the language of the claims.

The claim is indefinite and vague because from the claim it is not clear how the chimeric protein is linked to the polynucleotide or what are all the components present. And further the dependent claims recite 'that the polynucleotide includes a linker sequence between the nucleotide sequence encoding the nucleotide binding portion and the nucleotide sequence encoding the target peptide portion. However, the nucleotide binding portion and the target peptide portion are part of the chimeric protein (according to claim 1), and also the nucleotide binding portion of the chimeric protein is bound by the nucleotide sequence motif of the polynucleotide. Thus, it is not clear where the linker is present. Applicants are requested to recite clearly how all these different components are linked together and arranged spatially.

It is not clear what are the components of chimeric protein, does the chimeric protein has a nucleotide binding portion and binding domain of a nuclear steroid receptor and a target

Art Unit: 1639

peptide portion, or the chimeric protein has a nucleotide binding portion which is made of binding domain of a nuclear steroid receptor and a target peptide portion.

Further the claim is indefinite because it is not clear what is 'chimeric-protein encoding portion', does applicants mean that the polynucleotide encodes a chimeric protein; and if the chimeric protein encoded by the polynucleotide is same as the chimeric protein of chimeric-protein complex.

The claim recites that the **'polynucleotide comprises a chimeric-protein encoding portion and a nucleotide sequence motif'** which is specifically bound by said nucleotide binding portion....', it is not clear whether applicants mean that the chimeric-protein encoding portion and the nucleotide sequence motif (both) are bound by the nucleotide binding portion, or only the nucleotide sequence motif (both) are bound by the nucleotide binding portion.

The claim is indefinite because the claim recites that the nucleotide sequence motif is bound by the nucleotide binding portion of the chimeric protein, and do not recite that it is bound partially or some of the region of the nucleotide sequence motif.

The claim is also indefinite by reciting that 'at least the chimeric protein encoding portion of the recombinant polynucleotide not bound by the chimeric protein nucleotide binding portion...', it is not clear what does applicants mean by at least a portion of the chimeric protein encoding portion not bound by the nucleotide binding portion. Further the claim recites 'a binding moiety which is protein able to bind to polynucleotides....' does applicants mean that a

Art Unit: 1639

portion of the chimeric protein encoding portion is protected by a binding moiety which is a protein. And it is not clear what does applicants mean by 'irrespective of nucleotide sequences.'

The claim has several insufficient antecedent basis limitations . 'the recombinant polynucleotide' in line 6; 'the nucleotide sequence' in line 14.

Claim 3 recites the limitation "said binding moiety" . There is insufficient antecedent basis for this limitation in the claim or in claim 1.

Response to Arguments

15. Applicant's arguments filed on 8/23/02, regarding the rejection of claims over Schatz et al, have been fully considered but they are not persuasive.

Applicants argue that Schatz et al does not disclose nor suggest a synthetic construct where at least a portion of the recombinant polynucleotide which encodes a portion of the associated chimeric protein is protected by a protein which is not specific to the nucleotide thereby protected.

Applicants arguments have been considered but are not persuasive, because applicants arguments are based on certain features (i.e., a portion of the recombinant polynucleotide which encodes a portion of the associated chimeric protein is protected by a protein) which are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Art Unit: 1639

The instant claim recites that “..... said recombinant polynucleotide comprises a chimeric-protein encoding portion and a nucleotide sequence motif **which is specifically bound by said nucleotide binding portion**, and wherein *at least the chimeric- encoding* portion of the recombinant polynucleotide **not bound by the chimeric protein nucleotide binding portion** is protected by a binding moiety” That is the claim recites that certain portions of the chimeric-protein encoding portion of the recombinant nucleotide **not bound** by the nucleotide binding portion is protected by a binding moiety. However, in the claimed composition does not require to have a **portion of chimeric-protein encoding portion which is not bound by the nucleotide binding portion** as in applicants arguments. The claim does not recite that the chimeric-protein encoding portion of the recombinant polynucleotide has two portions, one is bound by the nucleotide binding portion and the other is unbound by the nucleotide binding portion. Thus, for the reasons of record the rejections of record have been maintained.

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1639

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Ponnaluri whose telephone number is (703) 305-3884. The examiner is on *Increased Flex Schedule* and can normally be reached on Monday to Friday from 7.00 AM to 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

P. Ponnaluri
Primary Patent Examiner
Technology Center 1600
Art Unit 1639
07 February 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER